

【Title】 Administrative Measures for National Food Safety Standards [Effective]

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The Administrative Measures for National Food Safety Standards, which were adopted at the executive meeting of the Ministry of Health on September 20, 2010, are hereby promulgated and shall come into force on December 1, 2010.

Chen Zhu, Minister

October 20, 2010

Administrative Measures for National Food Safety Standards

Chapter I General Provisions

Article 1 These Measures are formulated in accordance with the Food Safety Law of the People's Republic of China (hereinafter referred to as Food Safety Law) and the Regulation on the

Implementation thereof for the purpose of regulating the formulation and revision of national food safety standards.

Article 2 The formulation of national food safety standards shall aim to protect public health, and be based on the results of food safety risk assessment, so as to achieve scientificity, reasonability, openness, transparency, safety and reliability thereof.

Article 3 The Ministry of Health shall be responsible for the formulation and revision of national food safety standards.

The Ministry of Health shall set up a Review Committee for National Food Safety Standards (hereinafter referred to as the “Review Committee”), which shall be responsible for examining the draft national food safety standards, and provide advisory opinions for the work on national food safety standards. The Review Committee shall consist of professional sub-committees and the Secretariat.

Article 4 The formulation and revision of national food safety standards shall include planning, plan, initiation, drafting, examination, approval, issuance, amendment, review, etc.

Article 5 Citizens, legal persons and other organizations shall be encouraged to participate in the formulation and revision of national food safety standards and put forward comments and suggestions.

Chapter II Planning, Plan and Initiation

Article 6 The Ministry of Health shall, jointly with the agriculture administrative department, quality supervision department, industry and commerce administrative department, state food and drug administrative department, commerce department, industry and information technology department

and other departments under the State Council, formulate planning for national food safety standards and implementation plans thereof.

Article 7 The planning for national food safety standards and the implementation plans thereof shall specify the recent development objectives, implementation programs and guarantee measures for national food safety standards, etc.

Article 8 The Ministry of Health shall, in accordance with the planning for national food safety standards and the implementation plans thereof and in light of the needs of the food safety work, work out plans for formulation and revision of national food safety standards.

Article 9 Where the relevant department considers that the field under its supervision needs a national food safety standard, it shall, prior to the preparation of the plan for the formulation and revision of national food safety standards each year, put forward project initiation proposals to the Ministry of Health, which shall include important issues to be solved, backgrounds and reasons for the project initiation, the basis for monitoring and assessment of existing food safety risks, and candidates for the drafting of the standard. And the project initiation proposals shall be sequenced according to their priorities.

Any citizen, legal person or any other organization may put forward proposals for initiation of national food safety standards.

Article 10 National food safety standards that are proposed to be initiated shall comply with Article 20 of the Food Safety Law.

Article 11 The Review Committee shall, in accordance with the needs of the work on food safety standards, make research on the proposals for the initiation of national food safety standards, and put forward advisory opinions on the formulation of plans for formulation and revision of national food safety standards to the Ministry of Health.

Article 12 The Ministry of Health shall, prior to the announcement of the planning, implementation plan and formulation and revision plans for national food safety standards, solicit opinions from the public.

Article 13 Plans for formulation and revision of national food safety standards may be adjusted according to actual needs during the process of implementation.

According to results of the food safety risk assessment and major problems found in the food safety supervision, the items of formulation and revision of national food safety standards may be supplemented in an urgent manner.

Chapter III Drafting

Article 14 The Ministry of Health shall choose through tendering, entrustment, etc. the best entity with corresponding technical capacity to undertake the drafting of national food safety standards.

Article 15 Research institutions, educational institutions, academic groups, industry associations and other entities are encouraged to establish a collaborative group for standard drafting to jointly draft standards.

Article 16 An entity undertaking the drafting of standards shall conclude a project entrustment agreement on the formulation or revision of national food safety standards with the competent department or bureau of food safety under the Ministry of Health.

Article 17 The drafting of national food safety standards shall be based on results of the food safety risk assessment and risk assessment results of the quality and safety of edible agricultural products,

give full consideration to China's social and economic development level and needs of actualities, and consult relevant international standards and results of the international food safety risk assessment.

Article 18 A standards-drafting entity and the person in charge of the drafting shall, during the drafting process, carry out in-depth investigation and research to ensure the scientificity and authenticity of the drafting of standards. After the standards are drafted out, opinions of users of the standards, research institutions, industries, enterprises, consumers, experts, regulatory departments and other walks of life shall be solicited, with explanation on the formulation of standards provided to them.

Article 19 The drafting entity shall complete the drafting and opinion solicitation within the time limit as prescribed in the entrustment agreement, and submit the materials for examination to the Secretariat of the Review Committee (hereinafter referred to as the “Secretariat”) in a timely manner.

Chapter IV Examination

Article 20 The drafts of national food safety standards shall be examined in accordance with the following procedures:

- (1) Preliminary examination by the Secretariat;
- (2) Examination by the meeting of the professional sub-committees under the Review Committee; and
- (3) Deliberation by the directors' meeting of the Review Committee.

Article 21 The preliminary examination conducted by the Secretariat on the draft of national food safety standards shall cover the integrity, standardization, and consistency with the entrustment agreement.

Article 22 The standards that have passed the preliminary examination by the Secretariat shall be published on the website of the Ministry of Health for public comments. The period for solicitation of public comments shall be two months generally.

Article 23 The Secretariat shall deliver the feedback collected to the drafting entity, and the latter shall research on the feedback, improve the draft standards for examination, and give reasons for rejected opinions.

Article 24 The professional sub-committees shall be responsible for the examination of the scientificity and practicality of standards. In examining the standards, there shall be two-thirds of members or more present. The examination shall be conducted by consensus. When consensus can not be reached, vote shall be made on the basis of sufficient discussion. Consent from three-quarters of attending members or more shall be deemed that the standards have passed the examination.

The professional sub-committees shall prepare minutes, recording the discussion, major different opinions and the handling thereof.

As for the standards that failed to pass the examination, the professional sub-committee shall issue a written document to the drafting entity, giving reasons for disapproval and putting forward opinions for revision. The entity drafting the standards shall submit the revised version for examination again.

For standards which have passed the examination in principle but need to be revised, the Secretariat shall revise them according to examination opinions; the professional sub-committee may, in accordance with the actual situation, decide to conduct a meeting examination or letter examination of the revised standards.

Article 25 Standards which have passed the examination by the professional sub-committee shall be submitted to the directors' meeting of the Review Committee for deliberation after the chairman of the professional sub-committee has signed examination opinions.

Article 26 For draft standards deliberated and adopted at the directors' meeting of the Review Committee, the Chief Technologist of the Review Committee shall sign deliberation opinions.

For standards which fail to be adopted through deliberation, the Review Committee shall issue written opinions and give reasons for disapproval.

If it is decided through deliberation to revise the standards for reexamination, the Secretariat shall, according to the opinions on revision put forward by the Review Committee, organize the drafting entity to make revision and submit the revised version for reexamination.

Article 27 After the standards are adopted through deliberation, the drafting entity shall submit all the materials necessary for approval within the time limit as specified by the Secretariat.

Article 28 The Secretariat shall review the materials submitted for approval, and submit them to the Health Supervision Center under the Ministry of Health.

Article 29 The Health Supervision Center under the Ministry of Health shall, in accordance with examination opinions of professional sub-committees and deliberation opinions of the directors' meeting of the Review Committee, review contents and format of the materials on standards for approval, put forward review opinions and feed them back to the Secretariat.

The standards which have passed the review shall be submitted by the Health Supervision Center under the Ministry of Health to the Ministry of Health.

Article 30 In case of any special circumstance, the Ministry of Health may adjust the time limit for solicitation of public opinions on the drafts of national food safety standards, and the drafts may be directly subject to the joint examination by the meeting of the professional sub-committees and the directors' meeting of the Review Committee.

Article 31 Drafts of national food safety standards shall be submitted to the World Trade Organization (WTO) in accordance with relevant provisions.

Chapter V Approval and Issuance

Article 32 Standards which have passed the examination shall be issued in the form of announcement of the Ministry of Health.

Article 33 National food safety standards shall be published on the website of the Ministry of Health within 20 workdays from the date of issuance for the consultation of the general public free of charge.

Article 34 The power to interpret national food safety standards shall remain with the Ministry of Health. The interpretations on national food safety standards shall be published in the form of documents of the Ministry of Health, and shall have the same effect as national food safety standards.

Chapter VI Revision and Review

Article 35 After national food safety standards are issued, if some contents need to be adjusted, the revision list of national food safety standards shall be released in the form of announcement of the Ministry of Health.

Article 36 After national food safety standards are implemented, the Review Committee shall conduct review in good time, and put forward proposals for continuous effectiveness, revision or abolishment. National food safety standards that need to be revised shall be timely included in the initiation plan for the revision of national food safety standards.

Article 37 The Ministry of Health shall organize the Review Committee, provincial health administrative departments and relevant entities to conduct follow-up evaluation on the implementation of standards.

Any citizen, legal person or any other organization may put forward comments and suggestions on the problems existing in the implementation of the standards.

Chapter VII Supplementary Provisions

Article 38 Funds needed for formulation and revision of national food safety standards shall be included in financial budget arrangements, and be managed in accordance with relevant financial systems of the state and the administrative measures for special funds.

Article 39 National food safety standards issued shall belong to scientific and technological achievements and shall be taken as the basis for the appraisal of professional and technical qualifications of the main drafter of the standards.

Article 40 The formulation and revision of the standards for residues of pesticides and veterinary drugs in food shall be governed by relevant provisions of the Ministry of Health and the Ministry of Agriculture.

The numbering of national food safety standards shall be implemented according to the opinions from the consultation between the Ministry of Health and the Standardization Administration and relevant provisions.

Article 41 The formulation and revision of local food safety standards may be governed analogically by these Measures.

Article 42 These Measures shall come into force on December 1, 2010.